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PTO/SB/21 (02-04)

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TRANSMITTAL FORM <i>(to be used for all correspondence after initial filing)</i>	Application Number	10/760,100	
	Filing Date	01/16/2004	
	First Named Inventor	Jonathan C. Heller	
	Art Unit	1641	
	Examiner Name	Not yet assigned	
Total Number of Pages in This Submission	7	Attorney Docket Number	29191-707.501

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance communication to Technology Center (TC)
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<input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53		

SIGNATURE OF APPLICANT, ATTORNEY OR AGENT	
Firm or Individual name	U. B. Peter Eng, Reg. No. 39,666, WILSON SONSINI GOODRICH & ROSATI
Signature	
Date	September 30, 2005

Express Mail Date: September 30, 2005
Express Mail Label No.: EV518897321US

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PATENT
Attorney Docket No. 29191-707.501

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s): Jonathan C. HELLER, et al.

Serial Number: 10/760,100

Filing Date: January 16, 2004

Title: ASSAY CUSTOMIZATION

Group Art Unit: 1641

Examiner: Not yet assigned

CONFIRMATION NO: 7363

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §1.97

Sir:

Applicants hereby submit an Information Disclosure Statement along with attached form(s) PTO/SB/08A. A copy of each listed publication is being submitted, if required, pursuant to 37 C.F.R. §§1.97-1.98, as indicated below.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in §1.56.

☒ 37 CFR §1.97(b). This Information Disclosure Statement should be considered by the Office because:

- ☐ (1) It is being filed within 3 months of the application filing date of a national application and is other than a continued prosecution application under §1.53(d);
-- OR --
- ☐ (2) It is being filed within 3 months of entry of a national stage as set forth in §1.491 in an international application;
-- OR --
- ☒ (3) It is being filed before the mailing date of the first Office Action on the merits;
-- OR --
- ☐ (4) It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under §1.114.

☐ 37 CFR §1.97(c). Although this Information Disclosure Statement is being filed after the period specified in 37 CFR §1.97(b), above, it is filed before the mailing date of the earlier of (1) a final office action under §1.113, (2) a notice of allowance under §1.311, or (3) an action that otherwise closes prosecution on the merits, this Information Disclosure Statement should be considered because it is accompanied by one of:

- ☐ a certification as specified in §1.97(e) provided concurrently herewith;
-- OR --
- ☐ a fee of \$180.00 as set forth in §1.17(p) authorized below, enclosed, or included with the payment of other papers filed together with this statement.

☐ 37 CFR §1.97(d). Although this Information Disclosure Statement is being filed after the mailing date of the earlier of (1) a final office action under §1.113 or (2) a notice of allowance under §1.311, it is being filed before payment of the issue fee and should be considered because it is accompanied by:

- A. a certification as specified in §1.97(e); and
- B. a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this Statement.

☐ 37 CFR §1.97(e). A certification signed by an Attorney of Record is provided herewith as required under 37 CFR §§1.97(b) and (c).

☒ 37 CFR §1.98(a)(2). The content of the Information Disclosure Statement is as follows:

- ☐ Copies of each of the references listed on the attached Form PTO/SB/08A are enclosed herewith.
-- OR --
- ☒ Copies of U.S. Patent Documents (issued patents and patent publications) listed on the attached Form PTO/SB/08A are NOT enclosed.

-- AND/OR --

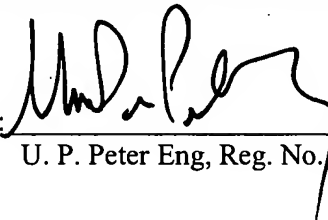
- ☒ Copies of Foreign Patent Documents and/or Non Patent Literature Documents listed on the attached Form PTO/SB/08A are enclosed in accordance with 37 CFR §1.98(a)(2).

-- AND/OR --

- ☐ Copies of pending unpublished U.S. patent applications are enclosed in accordance with 37 CFR §1.98(a)(2)(iii).
- ☒ 37 CFR §1.98(a)(3). The Information Disclosure Statement includes non-English patents and/or references.
- ☒ Pursuant to 37 CFR §1.98(a)(3)(i), a concise explanation of the relevance of each patent, publication or other information provided that is not in English is provided herewith.
- WO 2004/068130 and WO 2005/024409 were published in German. The English language abstracts and the drawings are sufficient to convey the scope of their disclosure.
- Should the Examiner believe that a complete translation of any of the above mentioned publication is necessary to understand its disclosure, Applicant(s) will endeavor to provide such translation at the Examiner's request.
- ☐ Pursuant to 37 CFR §1.98(a)(3)(ii), a copy of a translation of the non-English language reference(s) is provided herewith
- ☐ Attached are copies of search report(s) from corresponding patent application(s), submitted in accordance with MPEP 609 D in support of the attached certification under 37 CFR §1.97(e)(1).
- ☒ *Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No. 29191-707.501).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

By: 

U. P. Peter Eng, Reg. No. 39,666

Dated: September 30, 2005

650 Page Mill Road
Palo Alto, CA 94304-1050
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Customer No. 021971



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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/760,100
				Filing Date	01/16/2004
				First Named Inventor	Jonathan C. Heller
				Art Unit	1641
				Examiner Name	Not yet assigned
Sheet	1	of	3	Attorney Docket Number	29191-707.501

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
		US-5,652,427	07-29-1997	Whitehouse, et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
		WO 2004/068130 A2	08-12-2004	Mosaiques Diagnostics and Therapeutics AG (DE), et al.		✓
		WO 2004/102190	11-25-2004	Europroteome AG (DE), et al.		
		WO 2005/011474	02-10-2005	Correologic Systems Inc (US), et al.		
		WO 2005/020125	03-03-2005	Beyond Genomics Inc (US), et al.		
		WO 2005/024409	03-17-2005	Mosaiques Diagnostics and Therapeutics AG (DE), et al.		✓

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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				Art Unit	1641	
				Examiner Name	Not yet assigned	
Sheet	2	of	3	Attorney Docket Number		29191-707.501

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		FUNG, Eric T., et al., "Classification of cancer types by measuring variants of host response proteins using SELDI serum assays," <i>Int. J. Cancer</i> (2005) 115:783-789	
		KAJITA, Yoshihiro, et al., "Clinical Study on Increased Serum Thyroxine-Binding Globulin in Cancerous State," <i>Endocrinol. Japon</i> (1981) 28 (6): 785-791	
		KOO, Edward D., et al., "Amyloid diseases: Abnormal protein aggregation in neurodegeneration," <i>Proc. Natl. Acad. Sci.</i> (August 1990) Vol. 96: 9989-9990	
		KUNDIN, W.D., et al., "Cancer Serum Index: A useful Nonspecific Test as a Parameter in Multimodality Screening and Assessment of Patients With Cancer of the Prostate," <i>The Prostate</i> (1981) 2:207-217	
		LI, JINONG et al., "Detection of prostate cancer using serum proteomics pattern in a histologically confirmed population". <i>The Journal of Urology</i> (May 2004), 171:1782-1787.	
		MOBLEY, J.A., et al., "Monitoring The Serological Proteome: The Latest Modality in Prostate Cancer Detection," <i>The Journal of Urology</i> (July 2004) Vol. 172: 331-337	
		ORNSTEIN, David K., et al., "Serum Proteomic Profiling Can Discriminate Prostate Cancer From Benign Prostates in Men With Total Prostate Specific Antigen Levels Between 2.5 And 15.0 NG/ML," <i>The Journal of Urology</i> (October 2004) Vol. 172: 1302-1305	
		REIXACH, Natalia, et al., "Tissue damage in the amyloidoses: Transthyretin monomers and nonnative oligomers are the major cytotoxic species in tissue culture," <i>PNAS</i> (March 2, 2004) Vol. 101 No. 9: 2817-2822	
		ROBEY, Edwin L., et al., "Cancer Serum Index And Prostatic Acid Phosphatase For Detection Of Progressive Prostatic Cancer," <i>The Journal of Urology</i> (October 1985) Vol. 134: 787-790	
		ROSTENBERG, Israel, et al., "Gc Globulin and Prealbumin Serum Levels in Patients With Cancer and Benign Inflammatory Diseases and in Asymptomatic Smokers," <i>Journal of the National Cancer Institute</i> (February 1997) Vol. 62 No. 2:299-300	

Examiner signature		Date Considered	
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Sheet	3	of	3	Attorney Docket Number	29191-707.501

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		SASSI, Alexander P., et al., "An automated, sheathless capillary electrophoresis-mass spectrometry platform for discovery of biomarkers in human serum". <i>Electrophoresis</i> (2005), 26: pages unknown.	
		SCHWEIGERT, Florian J., et al., "Transthyretin, a Biomarker for Nutritional Status and Ovarian Cancer," <i>Cancer Research</i> (February 1, 2005) 65 (3):1114	
		THOMPSON, Ian M., et al., "Prevalence of Prostate Cancer among Men with a Prostate-Specific Antigen Level \geq 4.0 ng per Milliliter," <i>The New England Journal of Medicine</i> (May 27, 2004) Vol. 350 No. 22: 2239-2246	
		VEJDA, Susanne, et al., "Plasma from Cancer Patients Featuring a Characteristic Protein Composition Mediates Protection against Apoptosis," <i>Molecular & Cellular Proteomics</i> (2002):387-393	
		VILLANUEVA, Josep et al., "Serum peptide profiling by magnetic particle-assisted, automated sample processing and MALDI-TOF mass spectrometry". <i>Anal. Chem.</i> (March 15, 2004), 76(6):1560-1570.	
		WARD, A. Milford, et al., "Acute Phase Reactant proteins in Prostatic Cancer," <i>British Journal of Urology</i> (1977), 49: 411-418	
		ZHANG, Zhen, et al., "Three Biomarkers Identified from Serum Proteomic Analysis for the Detection of Early Stage Ovarian Cancer," <i>Cancer Research</i> (August 15, 2004) 64:5882-5890	
CO-PENDING/PUBLISHED/ISSUED PATENT MATTERS			
		HELLER, et al., U.S. Patent Application No. 11/178,245, entitled "Biological Patterns For Diagnosis And Treatment Of Cancer," filed 07-08-2005 (WSGR Reference No. 29191-729.201)	
		STULTS, et al., U.S. Patent Application No. 11/178,262, entitled "Systems and Methods for Discovery and Analysis of Markers," filed 07-08-2005 (WSGR Reference No. 29191-707.502)	

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